NEWPORT BEACH
HEADACHE & PAIN INSTITUTE

400 NEWPORT CENTER DR.
SUITE 701
NEWPORT BEACH CA 92660

T: 949.644.5800
F: 949.644.5813

October 3, 2000

Dockets Management Branch
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland

RE: Classification of Spinal Cord Stimulators

To Whom it May Concern:

My group currently implants a fair number of spinal cord stimulators. Specifically, in Southern California we perform more of these procedures than most other groups combined. We have found that this technology is very beneficial for selective patients, and the appropriate selection of these patients is critical to the success of the procedure.

When considering a patient for spinal cord stimulation, it is important to know both the psychological makeup of the individual, as well as the current pathophysiology which exists and creates the patient's pain symptoms. Spinal cord stimulation, although becoming more common these days, is still a significant advancement in the arena of pain management. We have become more routine with its ease of use and its applicability for a variety of patients.

The fear is that, with this increased complacence, the value will be undermined. Currently I am aware of two companies in the United States that provide spinal cord stimulators for implantation. They are both excellent companies and have performed a tremendous amount of research and development to provide not only a product which delivers good pain relief, but also a reliable product which dependably offers many years of service. As you know, the procedure itself is a surgical procedure and is not without risks. To implant any device that

would be compromised in its integrity would be unthinkable.

It is my understanding that these products might be considered by the FDA to be declassed from a Class III to a Class II product. I believe this would be a very bad idea. Specifically, we depend highly on the reliability of the companies currently providing this product. I would hate to see other imitators with less prudent clinical trials allowed to provide an alternative in that the long-term ramifications might be drastic.

I have no financial interest in either one of these companies. My only issue of interest is that my patients do well with these products, and I would hate to see anything compromise the care of these patients.

Please consider the request from me and other pain practitioners in Southern California in asking you not to change the class of implantable spinal cord stimulators from Class III to Class II.

If you have any questions or if you would like to have additional input on a personal note, I would be more than pleased to communicate with you by mail, telephone, or E-mail. Again, I thank you for your time regarding consideration of this issue.

Sincerely,

Richard M. Paicius, M.D.

RMP:skh

D: 10/3/00; T: 10/3/00

lace Labels in This Space

ptions: 1 UPS Tracking Label and your address label

Place the Tracking Label to the left of the address label

Stamp your UPS Shipper Number or place parcel register tape above the address label

2 UPS Air Shipping Document

3 UPS Waybill

1 OF 1

THE MAIL ROOM OF CORONA DEL MAR
949-673-2930
3535 E. COAST HWY.
CORONA DEL MAR CA 92625

SHIP TO: DOCKETS MGT. BRANCH (HFA-305)
5630 FISHERS LANE, ROOM 1061
U.S FOOD AND DRUG ADMIN.
ROCKVILLE MD 20852

MD 207 0-04

UPS NEXT DAY AIR

TRACKING #:1Z 932 E78 01 0180 5663

BILLING: PREPAID

Shipment ID: 566 PKG ID: 566

PC 1.9.1.73 UPS Therm 5.8 12/1999

International Shipping Notice - Carriage hereunder may be subject to the rules relating to liability and other terms and/or conditions established by the Convention for the Unification of Certain Rules Relating to International Carriage by Air (the "Warsaw Convention") and/or the Convention on the Contract for the International Carriage of Goods by Road (the "CMR Convention"). These commodities, technology or software were exported from the U.S. in accordance with the Export Administration Regulations. Diversion contrary to U.S. law prohibited. For stopping places, call 1-800-782-7892. United Parcel Service, Louisville, KY

The Next Day Air Letter is to be used for document shipments only.
There is no limit on weight or the number of pages you may enclose.

Call 1-800-PICK-UPS (1-800-742-5877) or visit our Web site at www.ups.com.